

REMARKS

Applicant respectfully requests entry of the above amendments. Claims 11, 13-16, 19, and 28-29 are pending in this application. Claims 11, 13-16, and 19 were previously presented. Claims 28 and 29 were renumbered from 29 and 30, respectively, due to a prior numbering error, and are presented as “currently amended”. Claims 1-10, 12, 17-18, and 20-27 were previously cancelled. No new matter was added with this amendment.

Claim Objection

In the previous amendment, Applicant cancelled claims 20-28 and added new claims 29 and 30. However, the last cancelled claim was actually 27, not 28. Therefore, Applicant renumbered claims 29 and 30 to claims 28 and 29, respectively, to correctly reflect the actual number of claims. Therefore, the objection is deemed moot and Applicant respectfully requests that said objection be withdrawn.

Claim Rejections

Rejection based on 35 USC §103(a) / §102(e) - Disqualifying under 35 USC §103(c)

The Office Action recites Bronk, et. al., US Patent Application Publication No. US2003/0139443 A1 as art against the instant invention. Applicant respectfully requests that the citation, Bronk, be disqualified as prior art under 35 USC §103(c), since the citation constitutes prior art only under 35 USC §102(e), and is not anticipatory; (MPEP 76.02(l)(1) and 706.02(l)(2)). Under §103(c), “subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102...shall not preclude patentability under this section where the subject matter and the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person”. The Bronk application and the claims of the instant invention, at the time the invention was made, were commonly and wholly owned by the same organization, i.e., Pfizer Inc. Further, the named inventors in the Bronk citation and the instant invention both had an obligation of assignment to Pfizer Inc. Hence, since the subject matter of Bronk and the instant invention were commonly owned at the time of invention, the reference cited by Examiner cannot be used as 102(e) art. Based on this

premise, Applicant respectfully requests that the Bronk citation be disqualified as §102(e) art for purposes of the obviousness rejection under §103(a).

Rejection based on §103(a)

Based on the aforementioned Bronk remarks, the Office Action can only rely on Giles-Komar et. al., (US Patent No. 7,163,681) and Ono et. al., (Eur. J. Pharm. Sci. 1999) as alleged art for the §103(a) rejection. Therefore, the Examiner's arguments which fully envelop Bronk (US2003/0139443) cannot stand and the art remaining does not create *prima facie* obvious.

Giles-Komar recites isolated human anti-integrin α -V subunit antibodies, immunoglobulins, and cleavage products, compositions thereof, for the treatment of cell adhesion diseases involving α -V integrin mediated angiogenesis. Compositions include an integrin molecule and a suitable carrier or diluent, including cyclodextrins and/or preservatives. The citation does not disclose NK-1 antagonists, particularly the compound of Formula 1a, as an element of the specification.

Ono recites complexation issues relative to the use of cyclodextrins, particularly as they relate to the solubility and permeation of phenacetin and various benzoic acids. Phenacetin and the benzoic acid derivatives were employed for modeling complexation because they were known to form 1:1 inclusion complexes with β -cyclodextrins thereby making modeling assumptions simple. Overall, modeling requires the determination of stability- and permeation-rate constants in free and complexed fractions. As described in Per Ono, cyclodextrin complex permeation rates are significantly affected by the presence of second guest molecules because of competitive inclusion. Therefore, based on the physicochemical and biological properties of a drug, stability constants, permeation rate constants, and competitive inclusion complexation stoichiometry of active drug(s), preservatives, excipients, and cyclodextrins, the skilled artisan would not be able to ascertain the pharmaceutical composition of the instant invention without undue experimentation.

In light of the aforementioned, Applicant disagrees that it would be obvious for a skilled artisan to prepare a pharmaceutical composition, as claimed, in light of Giles-Komar and Ono. In *KSR Intl. v. Teleflex*, U.S. 550 U.S. 398; 127 S. Ct. 1727; 167 L. Ed. 2d 705; 2007, the court noted that an invention may have been obvious when there was a design

need or market pressure to solve a problem and there was a finite number of identified, predictable solutions. Neither Giles-Komar or Ono provide any disclosure of using NK-1 antagonists. These citations disclose isolated human anti-integrin α -V subunit antibodies, immunoglobulins, and cleavage products, phenacetin, and various benzoic acids. There is an infinite number of drugs and compounds that could be formulated with cyclodextrin. Further, cyclodextrin complexation depends on multiple physiochemical attributes of the compound(s) used. Overall, the skilled artisan could not have predicted the formulation of the instant invention with any certainty of success in view of Giles-Komar and Ono. Therefore, the rejection is deemed moot and Applicant respectfully requests that the rejection be withdrawn and the claims be allowed to grant

Conclusion

Applicant respectfully requests that this amendment be entered, and that said objection and rejection be withdrawn. Applicant believes the application to be in condition for allowance, and respectfully requests an early and favorable action.

Respectfully submitted,



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Date: July 30, 2009
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